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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,151	01/26/2001	Danilo D. Lasic	55325-8169.US00	9729

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,151	Applicant(s) LASIC ET AL.	
	Examiner Gollamudi S Kishore, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

The amendment filed on 2-5-04 is acknowledged.

Claims included in the prosecution are 1, 3-9 and 16.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Upon consideration, the rejection of claims over EP 0177 223 is withdrawn.

2. Claims 1, 3-6, 8-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 551 169.

EP discloses a method of preparation of liposomes containing a supersaturated solution of a water-soluble drug (note the abstract, Example 3 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that nowhere does Yamamoto teaches selection of liposome sizes in order to maintain the compound in the form of a supersaturated solution. This argument is not persuasive since according to the reference, the supersaturated solution is at the room temperature (see abstract). This implies that the

Art Unit: 1615

compound is not in a precipitated state and this in turn means that the liposomes in the reference have selected liposomal sizes. Applicant arguments pertain to the motive behind the prior art process of encapsulating the supersaturated solution and instant motive. These arguments are not found to be persuasive since the process and the product formed are the same irrespective of the motivation of employing liposomes in instant case.

Applicants' arguments have been fully considered, but are not found to be persuasive. As applicants themselves recognize, EP (Yamamoto) teaches the drug in EITHER supersaturated state or in the form of crystals. That means the Yamamoto must have analyzed the liposomes to see whether there is any precipitation in the liposomes containing the supersaturated solution. Since these liposomes containing the supersaturated solutions were analyzed and found to contain no precipitate, the selection of the liposomes is implicit. In essence, instant claims do not distinguish over the prior art's teachings.

3. Claims 1, 3-9 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/07409.

WO 98 discloses a method of preparation of liposomes containing supersaturated solution of an active compound. The liposomes further contain a hydrophilic polymer (PEG) (note the abstract, page 2 line 15 through page 3, line 24, page 6, lines 14-26, page 12, lines 4-21, Example 3 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicants' arguments once again pertain to the lack of teachings in Abra

Art Unit: 1615

of analyzing the liposomes as a function of size for the presence or absence of precipitated compound. These arguments are not found to be persuasive since as with EP, applicants recognize that the reference teaches entrapment of the active agent EITHER in the dissolved or precipitated state. Therefore, the same response as above is applicable.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 551 169 in combination with Woodle (5,013,556) of record.

What is lacking in EP is the inclusion of a hydrophilic polymer in the liposome compositions.

Woodle discloses that the inclusion of a hydrophilic polymer enhances the circulation time of the liposomes (note the abstract).

The inclusion of a hydrophilic polymer in the liposomes of EP references would have been obvious to one of ordinary skill in the art because it enhances the circulation time of the liposomes as taught by Woodle.

Applicants' arguments have been fully considered but are not found to be persuasive. Although applicants admit that Woodle teaches the use of hydrophilic polymer, they argue that it does not overcome the deficiencies of the primary documents. Applicant's arguments with regard to the deficiencies EP references have been addressed above.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, PhD whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1234.



Gollamudi S Kishore, PhD
Primary Examiner
Art Unit 1615

GSK